AMENDMENTS

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in this application.

Listing of Claims:

1. (Currently amended) A milnacipran formulation that provides pulsatile release of milnacipran wherein the formulation comprises:
(a) an immediate release dosage unit comprising a first dose of milnacipran that is released substantially immediately following oral administration of the formulation to a patient resulting in a first plasma level peak at a time between approximately 0.05 hours to less than 3 hours following oral administration;
(b) a first delayed release dosage unit comprising a second dose of milnacipran resulting in a second plasma level peak at a time of more than 3 hours to less than 14 hours following oral administration of the formulation; and optionally
(c) a second delayed release dosage unit comprising a third dose of milnacipran resulting in a third plasma level peak at a time between approximately 5 hours to less than 18 hours following oral administration of the formulation; and
wherein there is a lag time where there is substantially no release of milnacipran between the release of the immediate release dosage unit and the release of the first delayed release dosage unit
~~to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to side effects side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation~~.

2. (Currently amended) The milnacipran formulation according to claim 1, wherein the formulation produces a therapeutic effect over approximately 24 hours when administered to a patient in need thereof with diminished incidence or reduced intensity

relative to side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation~~wherein the side effect is nausea~~.

3. (Currently amended) The ~~malnacipran~~milnacipran formulation according to claim [[1]]2, wherein the side effects are ~~selected from the group consisting of~~ nausea, vomiting, headache, tremulousness, anxiety, panic attacks, palpitations, urinary retention, orthostatic hypotension, diaphoresis, chest pain, rash, weight gain, back pain, constipation, vertigo, increased sweating, agitation, hot flushes, tremors, fatigue, somnolence, dyspepsia, dysoria, nervousness, dry mouth, abdominal pain, irritability, ~~and~~ or insomnia.

4. (Cancelled).

5. (Cancelled).

6. (Currently amended) The milnacipran formulation according to claim 1 providing milnacipran blood plasma levels ~~that are characterized by~~ having a C_{max} below approximately 3000 ng/ml.

7. (Currently amended) The milnacipran formulation according to claim 6 providing milnacipran blood plasma levels ~~that are characterized by~~ having a C_{max} below approximately 2000 ng/ml.

8. (Currently amended) The milnacipran formulation according to claim 6 providing milnacipran blood plasma levels ~~that are characterized by~~ having a C_{max} below approximately 1000 ng/ml.

9. (Currently amended) The milnacipran formulation according to claim 1 further comprising at least one other ~~active~~ compound selected from the group consisting of analgesics, anti-inflammatory drugs, antipyretics, antidepressants, antiepileptics, antihistamines, antimigraine drugs, antimuscarinics, anxioltyics, sedatives, hypnotics,

antipsychotics, bronchodilators, anti asthma drugs, cardiovascular drugs, corticosteroids, dopaminergics, electrolytes, gastro-intestinal drugs, muscle relaxants, nutritional agents, vitamins, parasympathomimetics, stimulants, anorectics, and anti-narcoleptics.

10. (Original) The milnacipran formulation according to claim 9 comprising one or more compounds selected from the group consisting of aceclofenac, acetaminophen, adomexetine, almotriptan, alprazolam, amantadine, amcinonide, aminocyclopropane, amitriptyline, amolodipine, amoxapine, amphetamine, aripiprazole, aspirin, atomoxetine, azasetron, azatadine, beclomethasone, benactyzine, benoxaprofen, bermoprofen, betamethasone, bicifadine, bromocriptine, budesonide, buprenorphine, bupropion, buspirone, butorphanol, butriptyline, caffeine, carbamazepine, carbidopa, carisoprodol, celecoxib, chlordiazepoxide, chlorpromazine, choline salicylate, citalopram, clomipramine, clonazepam, clonidine, clonitazene, clorazepate, clotiazepam, cloxazolam, clozapine, codeine, corticosterone, cortisone, cyclobenzaprine, cyproheptadine, demexiptiline, desipramine, desomorphine, dexamethasone, dexanabinol, dextroamphetamine sulfate, dextromoramide, dextropropoxyphene, dezocine, diazepam, dibenzepin, diclofenac sodium, diflunisal, dihydrocodeine, dihydroergotamine, dihydromorphine, dimetacrine, divalproxex, dizatriptan, dolasetron, donepezil, dothiepin, doxepin, duloxetine, ergotamine, escitalopram, estazolam, ethosuximide, etodolac, femoxetine, fenamates, fenoprofen, fentanyl, fludiazepam, fluoxetine, fluphenazine, flurazepam, flurbiprofen, flutazolam, fluvoxamine, frovatriptan, gabapentin, galantamine, gepirone, ginko bilboa, granisetron, haloperidol, huperzine A, hydrocodone, hydrocortisone, hydromorphone, hydroxyzine, ibuprofen, imipramine, indiplon, indomethacin, indoprofen, iprindole, ipsapirone, ketaserin, ketoprofen, ketorolac, lesopitron, levodopa, lipase, lofepramine, lorazepam, loxapine, maprotiline, mazindol, mefenamic acid, melatonin, melitracen, memantine, meperidine, meprobamate, mesalamine, metapramine, metaxalone, methadone, methadone, methamphetamine, methocarbamol, methyldopa, methylphenidate, methylsalicylate, methysergid(e), metoclopramide, mianserin, mifepristone, milnacipran, minaprine, mirtazapine, moclobemide, modafinil, molindone, morphine, morphine hydrochloride, nabumetone, nadolol, naproxen, naratriptan, nefazodone, neurontin, nomifensine, nortriptyline,

olanzapine, olsalazine, ondansetron, opipramol, orphenadrine, oxaflozane, oxaprazin, oxazepam, oxitriptan, oxycodone, oxymorphone, pancrelipase, parecoxib, paroxetine, pemoline, pentazocine, pepsin, perphenazine, phenacetin, phendimetrazine, phenmetrazine, phenylbutazone, phenytoin, phosphatidylserine, pimozide, pirlindole, piroxicam, pizotifen, pizotyline, pramipexole, prednisolone, prednisone, pregabalin, propanolol, propizepine, propoxyphene, protriptyline, quazepam, quinupramine, reboxitine, reserpine, risperidone, ritanserin, rivastigmine, rizatriptan, rofecoxib, ropinirole, rotigotine, salsalate, sertraline, sibutramine, sildenafil, sulfasalazine, sulindac, sumatriptan, tacrine, temazepam, tetrabenozine, thiazides, thioridazine, thiothixene, tiapride, tiasipirone, tizanidine, tofenacin, tolmetin, toloxatone, topiramate, tramadol, trazodone, triazolam, trifluoperazine, trimethobenzamide, trimipramine, tropisetron, valdecoxib, valproic acid, venlafaxine, viloxazine, vitamin E, zimeldine, ziprasidone, zolmitriptan, zolpidem, zopiclone and isomers, salts, and combinations thereof.

11. (Original) The milnacipran formulation according to claim 1, wherein the milnacipran is in the form of a therapeutically equivalent dose of dextrogyral or levrogyral enantiomers of the milnacipran or pharmaceutically acceptable salts thereof.

12. (Original) The milnacipran formulation according to claim 1, wherein the milnacipran is in the form of a therapeutically equivalent dose of a mixture of milnacipran enantiomers or pharmaceutically acceptable salts thereof.

13. (Cancelled).

14. (Previously presented) The milnacipran formulation according to claim 1, wherein the milnacipran is in the form of a therapeutically equivalent dose of para-hydroxy-milnacipran (F2782), individual enantiomers of para-hydroxy-milnacipran, mixtures of enantiomers of para-hydroxy-milnacipran, or pharmaceutically acceptable salts thereof.

15. (Currently amended) The milnacipran formulation according to claim 1, wherein said first delayed release dosage unit and/or said second delayed release dosage unit comprise ~~comprising~~ an enteric coating.

16. (Currently amended) The milnacipran formulation according to claim 1, ~~wherein the administrable milnacipran unit dose is from 25 to 500 mg~~wherein the formulation comprises 25 to 500 mg of milnacipran.

17. (Currently amended) The milnacipran formulation according to claim 1, ~~wherein the administrable milnacipran unit dose is from 200 to 500 mg~~wherein the formulation comprises 200 to 500 mg of milnacipran.

18. (Cancelled).

19. (Currently amended) The milnacipran formulation according to claim 1 wherein the immediate release dosage unit and the first delayed release dosage unit are each in the form of ~~comprising~~ a mixture of beads or particles wherein the particles ~~releasing~~ release drug at different times.

20. (Original) A kit comprising the milnacipran formulation of claim 1.

21. (Original) The kit of claim 20 comprising different dosage units of milnacipran to allow for dosage escalation.

22. (Cancelled).

23. (Cancelled).

24. (Cancelled).

25. (New) A milnacipran formulation that provides pulsatile release of milnacipran wherein the formulation comprises:

(a) an immediate release dosage unit comprising a first dose of milnacipran that is released substantially immediately following oral administration of the formulation to a patient resulting in the first plasma level peak at a time between approximately 0.05 hours to less than 3 hours following oral administration; and

(b) a delayed release dosage unit comprising a second dose of milnacipran resulting in a second plasma level peak at a time between approximately 5 hours to less than 18 hours following oral administration of the dosage form; and

wherein there is a lag time where there is substantially no release of milnacipran between the release of the immediate release dosage unit and the release of the delayed release dosage unit.

26. (New) A milnacipran formulation that provides pulsatile release of milnacipran wherein the formulation comprises:

(a) an immediate release dosage unit comprising a first dose of milnacipran that is released substantially immediately following oral administration of the formulation to a patient resulting in the first plasma level peak at a time between approximately 0.05 hours to less than 3 hours following oral administration;

(b) a first delayed release dosage unit comprising a second dose of milnacipran resulting in a second plasma level peak at a time more than 3 hours to less than 14 hours following oral administration of the formulation; and optionally

(c) a second delayed release dosage unit comprising a third dose of milnacipran resulting in the third plasma level peak at a time between approximately 5 hours to less than 18 hours following oral administration of the formulation;

wherein the formulation comprises 25 to 500 mg of milnacipran and wherein the formulation effects a C_{max} below approximately 3000 ng/mL; and

wherein there is a lag time where there is substantially no release of milnacipran between the release of the immediate release dosage unit and the release of the first delayed release dosage unit.

27. (New) The formulation of claim 26, wherein the formulation comprises 200 to 500 mg of milnacipran.

28. (New) The milnacipran formulation according to claim 1, wherein the immediate release dosage unit and the first delayed release dosage unit are each in the form of a tablet, wherein each tablet releases drug at different times.